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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,268	03/01/2004	Leo J. Romanczyk JR.	1010/100US3	3127
32260	7590	09/14/2006	EXAMINER	
NADA JAIN, P.C. 560 White Plains Road, Suite 460 Tarrytown, NY 10591			NUTTER, NATHAN M	
			ART UNIT	PAPER NUMBER

1711

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/790,268

Applicant(s)

ROMANCZYK ET AL.

Examiner

Nathan M. Nutter

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 August 2006 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-47, 55-61 and 67-75 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tempesta.

The reference to Tempesta teaches the use of proanthocyanidine polymers that may comprise the identical "flavenoid 3-ol units linked together through common C(4)-(6) (*sic*) and/or C(4)-C(8)," as herein recited, at the paragraph bridging column 1 to column 2. At column 1 (lines 13-20) the reference teaches the "proanthocyanidin polymers, having 2 to 30 flavenoid units in treating respiratory virus infections," i.e. used in a "therapeutically effective" amount, as recited in instant claims 33, 40, 47, 61 and 73.

Art Unit: 1711

Note the structures at columns 5-8. The Abstract teaches the use of isolated and synthesized forms of the compounds. The reference teaches the topical administration, intravenous administration, oral and nasal administrations at column 9 (lines 15-18) and the vaginal administration at column 38 (line 45) to column 39 (line 18).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-61 and 67-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,747,059. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the oligomers of procyanidin of the instant claims is within the recitations of the patented claims wherein the oligomers are of the same chemical structures having "interflavin linkages 4 $\Leftarrow$ 6 and/or 4 $\Leftarrow$ 8." It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the

Art Unit: 1711

patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious variant, since "administration," as recited in the claims, includes each of these.

Claims 27-61 and 67-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-25 of U.S. Patent No. 6,524,630. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the procyanidin oligomers recited in the instant claims is within the recitations of the patented claims wherein the oligomers may be of the same chemical structures. It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious variant, since "administration," as recited in the claims, includes each of these.

Claims 27-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,712,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the procyanidin oligomers recited in the instant claims is within the recitations of the patented claims wherein the oligomers may be of the same chemical structures. It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious

variant, since "administration," as recited in the claims, includes each of these. Since the reference is drawn to the use of an antineoplastic agent, the use of other known agents for this purpose would also be an obvious variant.

### ***Response to Arguments***

Applicant's arguments filed 21 December 2005 have been fully considered but they are not persuasive.

The reference to Tempesta, which teaches clearly the antiviral activity in the Title, the Abstract and variously throughout the reference for the use of proanthocyanidins, which broadly embraces and includes the procyanidins, and particularly those disclosed at the paragraph bridging column 1 to column 2. Since a reference is taken for the entirety of its teachings, to pick isolated teachings of a reference which lie outside of the scope of the claims in order to assert a difference would be improper. Applicants allege that

"claims 27-47, 55-61 and 67-75 do not recite compounds *per se*. Therefore, it is not sufficient to ask whether the compounds recited in these claims can be 'at once envisioned' from cols. 1-2 of Tempesta; the entire subject matter of the above Applicant's claims (i.e., pharmaceutical composition) must be at once envisioned from cols. 1-2 of Tempesta. In other words, in order to anticipate, cols. 1-2 of Tempesta must disclose some biological activity of Applicants' compounds. This is not the case."

Applicants are reminded that a reference is taken for the entirety of its teachings and not for isolated passages that applicants might rely upon to proffer patentability to the claims. It is pointed out that the instant claims, while they recite "(a) pharmaceutical composition," do not require any other constituents. The reference is clearly drawn to

Art Unit: 1711

administration of these compounds for their anti-viral activity which clearly would be in a pharmaceutical. Applicants have not shown why this wouldn't be true. As such, the claims are deemed anticipated by the teachings of the reference. The reference is clearly drawn to the biological activity of the compounds. Regardless that the reference does not present examples drawn to specific embodiments, these embodiments, as pointed out above, are embraced by the teachings of the patent. The paragraph bridging column 1 to column 2 clearly shows what is recited and claimed herein. Applicants have not explained why this isn't so. The formulae are easily envisaged since they are essentially taught therein.

The rejections of the claims under the judicially-created doctrine of obviousness-type double patenting over patents 6,747,059, 6,524,630 and 5,712,305 are being maintained. It is not relevant as to the filing dates of either reference since the questions of ownership may arise later. Timely filed Terminal disclaimers are required to overcome the reasons for the rejections as set out above.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1711

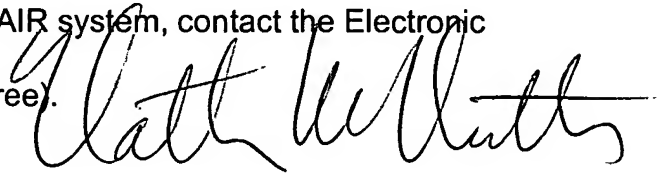
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan M. Nutter whose telephone number is 571-272-1076. The examiner can normally be reached on 9:30 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1711

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nathan M. Nutter  
Primary Examiner  
Art Unit 1711

nmn

10 September 2006